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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,796	03/13/2000	DOMINIQUE BRASSART	P99.2625	1391

7590 01/22/2002

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EXAMINER
AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/445,796	Brassart et al.
Examiner	**Art Unit**
Vera Afremova	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Jan 8, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);

(b) ☐ they raise the issue of new matter. (See NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

4. ☐ Applicant's reply has overcome the following rejection(s):

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☒ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: *none*
Claim(s) objected to: *none*
Claim(s) rejected: *11-23*

9. ☒ The proposed drawing correction filed on *Jan 8, 2002* a) ☒ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .

11. ☐ Other:

Attachment to Advisory Action

Amendment to specification which was filed on 1/08/2002 and which is directed to "Brief description of drawings" has been ~~entered~~ approved.

Correction to Drawings which is English translation has been approved.

Deposit

The deposit requirement for *Lactobacillus johnsonii* CNCM I-1225 has been met in the Paper No. 10 filed 6/04/2001.

Response to Arguments

Applicants' arguments filed 1/08/2002 have been fully considered but they are not persuasive.

With regard to the claim rejection under 35 U.S.C. 112, *second paragraph*, applicants appear to argue that the phrase *"lactobacilli"* encompasses representatives of the genus *Lactobacillus* and it excludes representatives of the genus *Bifidobacterium* (see response page 2). This is not found convincing in the light of the definitions in the as-filed specification encompasses the use of lactobacteria of other genera, for example: *Leuconostoc* (page 3, line 17). In addition, it appears from the applicants' disclosure that representatives of the genus *Bifidobacterium* are also regarded as "*lactobacilli*" or lactobacteria which are capable to produce effects as intended (page 2, line 7). Claims are not limited by the use of the Latin names of bacteria which are argued and which are intended.

With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by US 5,578,302 [B] or by US 5,494,664 [A] applicants argue that the cited references fail to disclose that the *in vivo* administration of lactobacteria improves mineral adsorption as intended by the present invention (see response pages 3-5). This is not found persuasive because the cited methods and the presently claimed method are one active step methods comprising one step of enterally administering to a mammal an identical composition with identical lactobacteria belonging to identical strain *Lactobacillus sp.* CNCM I-1225 {US'664 or US'302} at identical amount such as 10x7 to 10x8 CFU/ml {US'664}. Thus, the final result as disclosed and as claimed is inherently identical as the result of administration of identical composition with identical lactobacteria. In order to qualify as an anticipatory reference, the disclosure need not be express. Even failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation: In *Atlas Powder Co. v. IRECO, Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999). Thus applicants are incorrect in arguing that the anticipatory rejection is improper and must be "certain". A prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See id.; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re* King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of

ordinary skill in the art. See Titanium Metals, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id. at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See id. at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); Verdegaal Bros., 814 F.2d at 633.

With regard to the claim rejection under 35 U.S.C. 102(b)/103 and under 103 applicants appear to argue that the references by Yaeshima [IDS-3-AR] and Yoshida [U] fail to suggests functional equivalency between representatives of the genus *Lactobacillus* and representatives of the genus *Bifidobacterium*. For example: see response pages 5-8 and especially page 8, last paragraph, wherein applicants argue that bacteria of two different genera colonize distinctive areas of intestines and, thus, they provide different probiotic effects. This is not found convincing because the reference by Yaeshima [IDS-3-AR] teaches that representatives of *Bifidobacterium* are clearly shown to improve mineral absorption in vivo (page 41), that the representatives of both groups or genera such as *Lactobacillus* and *Bifidobacterium* reside in large intestines (page 36, col. 1, par. 1) are they are both thought to contribute to digestion and absorption (see page 36, paragraph bridging two col.). Therefore, there is a reasonable expectation in functional equivalency between the probiotic or other beneficial effects of two groups of bacteria.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

January 15, 2002.

V.A.

SANDRA E. SAUCIER
PRIMARY EXAMINER